

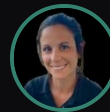
Rethink Your EU Breakthrough Device (BtX) Strategy

What MDCG 2025-9 changes about evidence planning, regulatory engagement, and lifecycle strategy.



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MDCG 2025-9

BtX

under MDR and IVDR

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EXECUTIVE SUMMARY

BtX has arrived in Europe. Is your evidence strategy ready?

MDCG 2025-9 introduces a structured framework for Breakthrough Devices (BtX) under the EU Medical Device Regulation (MDR) and In Vitro Diagnostic Regulation (IVDR).¹ But manufacturers expecting an EU version of the FDA Breakthrough Device Program may be planning around the wrong assumption. BtX does not create a separate regulatory pathway or lower the evidence required for market authorization. Instead, it introduces new opportunities for earlier engagement and a more lifecycle-based approach to evidence generation.

That distinction creates an important strategic question:

"How should manufacturers adapt development and evidence plans now to take advantage of BtX without creating new regulatory or post-market risk later?"

This white paper examines what MDCG 2025-9 changes, where uncertainty remains, and what medical device and IVD manufacturers should consider as the framework moves from guidance into practice.

OUR POSITION

BtX should not be treated as a shortcut to EU market authorization.

The bigger shift is in when evidence is generated and how it is sequenced across the product lifecycle. Manufacturers that identify BtX potential early can build regulatory engagement, pre-market evidence, and post-market commitments into one development strategy. Those that approach designation only as a way to accelerate approval may discover later that the evidence burden has shifted rather than disappeared.

The opportunity is not simply to move faster. It is to plan the evidence journey differently from the start.



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Understand what BtX changes for your development strategy

THIS WHITE PAPER EXPLORES

- How BtX eligibility and regulatory engagement may work in practice
- Where the EU approach differs from the FDA Breakthrough Device Program
- How evidence planning and post-market expectations could change

BACKGROUND

02

EU Breakthrough Device Eligibility

The regulatory gap MDCG 2025-9 was designed to fill, and the dual criteria that define breakthrough device eligibility in the EU.

The EU has historically lacked a dedicated framework for breakthrough medical technologies.

While MDR and IVDR are technology-neutral, their implementation has proven challenging for novel technologies without comparable ones, or devices addressing rare or high-risk conditions or early-stage innovations lacking extensive clinical data.

The new guideline MDCG 2025-9 addresses this gap by establishing a common interpretation framework for evaluating innovative devices while maintaining high standards of safety and performance.

So, what exactly is a BtX device in the EU?

For a device to be considered a BtX, it needs to meet both¹ of these criteria:

CRITERION 1 Novelty The device introduces a high degree of novelty with respect to the device technology, the related clinical procedure, and/or the application of the device in clinical practice.	CRITERION 2 Positive Clinical Impact The device is expected to provide clinical impact on patients or public health, for a life-threatening or irreversibly debilitating disease or condition, by either one of the following: - Offering a significant positive clinical impact on patient or public health compared to available alternatives and the state of the art, - or - Fulfilling an unmet medical need where there is an absence or insufficiency of available alternative options for that purpose.
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OF NOTE

The breakthrough status does not reduce regulatory requirements. The BtX is not a new classification, nor a fast-track approval pathway, nor an exemption from MDR/IVDR obligations.¹

ADVANTAGES

03

Realistic BtX Designation Benefits

What BtX designation can realistically deliver: earlier engagement, evidence flexibility, and potential assessment priority.

Although not an accelerated pathway per se, BtX provides several strategic advantages to MedTech manufacturers developing new innovative solutions for unmet clinical needs.

Early and Structured Regulatory Engagement

Manufacturers are encouraged to engage early with notified bodies, competent authorities and expert panels, which facilitates the alignment on clinical strategy and early identification of regulatory risks.

Early and structured engagement with notified bodies, competent authorities, and expert panels, as outlined in MDCG 2025-9, can substantially reduce regulatory uncertainty from the outset of development. By aligning clinical strategy, evidence requirements, and risk-mitigation approaches early, companies gain clearer visibility into what will be expected for conformity assessment and eventual market access. This upfront clarity helps prevent costly redesigns, delays, and unsuccessful submissions, key factors that make regulatory pathways appear high-risk.

For companies, and especially startups, this creates a more predictable development trajectory, strengthens credibility during due-diligence evaluations, and demonstrates a de-risked route toward CE marking. As a result, BtX can enhance investment readiness, shorten timelines, and build confidence among both internal decision-makers and external investors.¹²

It will also be important to observe how notified bodies implement this early-engagement model in practice, given their strict prohibition on providing consultancy. The guidance encourages more interaction, but the boundaries between permissible clarification and impermissible advice will need to be carefully managed to ensure both regulatory efficiency and continued independence of conformity-assessment activities.

Prioritization of Assessment

While MDCG 2025-9 indicates that BtX devices may benefit from prioritized review timelines and more focused interactions with regulators, it remains to be seen how this prioritization will be implemented in practice. The guidance signals an intention to streamline assessments for high-impact or innovative technologies, but the concrete mechanisms, such as resource allocation, review queues, or defined fast-track criteria, have not yet been detailed. Clarity on these operational aspects will be essential for companies, particularly startups, to understand how much acceleration they can realistically expect and how to integrate these potential efficiencies into their development and regulatory planning.

Flexible Evidence Generation

The framework supports a lifecycle-based approach: during pre-market one can demonstrate acceptable benefit-risk, and later in post-market generate confirmatory evidence. This flexibility is particularly relevant for AI-driven devices, precision medicine applications, and CDx and biomarker-driven diagnostics.¹³

It is encouraging to see this flexible evidence-generation model formally recognized, as it acknowledges that certain innovative technologies, especially those addressing unmet medical needs, may require post-market data to fully confirm clinical performance. Allowing part of the evidence package to mature after market entry can clearly accelerate access for patients while maintaining a controlled, lifecycle-based oversight framework.

Looking ahead, it will be important to observe how notified bodies interpret and operationalize this flexibility in practice. A key question will be how they define the acceptable level of pre-market evidence needed to support a positive benefit-risk determination, and whether these thresholds will be applied consistently across different notified bodies.

CHALLENGES

04

BtX Limits and Planning Realities

What the framework does not guarantee, and the operational realities manufacturers need to plan around before treating BtX as a development accelerator.

Despite its advantages, BtX introduces several challenges:

- Increased reliance on post-market data, as it requires strong data infrastructure and long-term follow-up strategies;
- Notified body capacity;²
- Lack of formal acceleration, i.e. no guaranteed timelines (as opposed to FDA pathways).

THE PILOT PROGRAMME

05

EMA Pilot Opens Early Dialogue

How the EMA's phased pilot creates a structured early engagement window, what manufacturers can realistically expect at each stage, and why it matters now.

The European Medicines Agency (EMA) launched a pilot programme in April 2026 to establish a structured pathway for expert panel support to manufacturers and notified bodies involved in breakthrough medical devices (BtX).⁴ The pilot is designed to:

- Facilitate early, high-quality scientific and regulatory advice for innovative medical devices
- Support designation and development of "breakthrough" devices
- Accelerate patient access to technologies addressing unmet medical needs, while maintaining robust safety and performance requirements

The programme will run in three phases (see table below) and provides free expert panel advice in two main areas:

ADVICE AREA 1 Designation support Guidance on whether a device qualifies as a breakthrough device.	ADVICE AREA 2 Development and conformity support Advice on implementing regulatory guidance.
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PHASE	SCOPE AND TIMING
Phase I (Ia & Ib)	Ongoing. Applies only to class III and class IIb active devices intended to administer or remove a medicinal product. EMA prioritises the following types of devices in phase Ia: cardiovascular devices and devices intended for children. Limited number of applications (5 selected). Manufacturers selected in Phase Ia who receive a positive opinion on the breakthrough status of their medical devices have the possibility to submit requests for advice as of 1 September 2026. This date marks the start of Phase Ib, when EMA accepts all applications within the scope of Phase I. ⁴
Phase II	Expected to start in Q1 2027. EMA extends designation and advice requests to all classes of medical devices. ⁴
Phase III	Expected to start in Q3 2027. EMA extends designation and advice requests to in vitro diagnostics (IVDs). ⁴

This pilot will be particularly valuable in helping regulators and notified bodies identify bottlenecks, refine processes, and calibrate expectations before full-scale deployment. It will give manufacturers of designated BtX devices access to priority scientific advice from EMA expert panels, beginning with an initial application window in May 2026. The outcomes of the pilot will ultimately shape how the BtX pathway is harmonized and integrated into routine conformity-assessment workflows.

It will be important to observe how the BtX framework is implemented and progressively refined based on feedback from the ongoing pilot phase, which will serve as the first real-world test of the model. This pilot is expected to generate practical insights into how flexible evidence generation, early engagement, and prioritization mechanisms operate in actual regulatory interactions. As experience accumulates, the framework may be adjusted to improve consistency, predictability, and operational feasibility across the EU.

EU VS. US: A FRAMEWORK COMPARISON

06

Global Strategy Must Align Both

A comparison that reframes the planning question: not which system is more favorable, but how manufacturers with global ambitions need to align strategy across both.

Compared to the FDA Breakthrough Device Program (US), the EU BtX focuses on lifecycle flexibility and emphasizes post-market evidence, while the FDA focuses on accelerated pre-market review. Key differences are summarized in the table below.¹⁵⁶

	EU (MDCG 2025-9)	US (FDA BREAKTHROUGH DEVICES PROGRAM)
Legal basis	Non-binding guidance document ¹	Law (§515B FD&C Act) – binding ^{5 6}
Definition	Both novelty and positive clinical impact required ¹	More effective treatment/diagnosis and one of the following: ^{5 6} • novelty • no approved or cleared alternatives • significant advantages • in the best interest of patients
Responsible body	Decentralized: EMA Expert Panels + Notified Body (NB) + National Competent Authorities. Greater coordination effort between stakeholders.	Centralized: FDA. Single point of contact.
Decision deadlines	≤ 60 days (targeted, not guaranteed) ¹	≤ 60 days (statutory guarantee) ⁵
Binding protocol agreement	No – advice with Expert Panel is recommended only ¹	Yes – Clinical Protocol Agreement ⁵
Priority review	Intended but NB-dependent capacity ^{2 7}	Guaranteed + extra FDA resources ⁵
Conditional approval	Formal certification with conditions (Art. 56(3)) ¹	Post-market commitments in PMA ⁵
Post-market (PMCF/PMPF)	Highly detailed: Post Market Clinical/Performance Follow-up (PMCF/PMPF) plan mandatory, PMCF/PMPF studies, registries for high-risk implants, participation in External Quality Assessment (EQA) schemes for IVDs, real-world data, regular CER/PER updates, increased NB surveillance. ¹	Post-market data collection as part of benefit-risk assessment. Less formalized than EU. ⁵
SME support	Explicit fair-fee & dialogue obligations (MDR) ¹	No specific programme provisions
EU funding access	EU4Health, EIC, Horizon Europe, InvestEU ^{1 7}	Not available via programme
HTA integration	Parallel Joint Scientific Consultation assessment available, helping companies to design studies that satisfy both regulatory approval and reimbursement expectations ^{1 4 8 9}	No HTA linkage
AI	Dedicated section, EU AI Act alignment	Not addressed
Programme maturity	Since Dec 2025 – limited operational experience	Established since 2016 – strong experience

STRATEGIC RECOMMENDATIONS FOR MANUFACTURERS

07

Six Moves for BtX Advantage

Six moves that translate BtX designation from a regulatory credential into a development and commercial advantage.

Success under the BtX framework depends on early planning, strong regulatory engagement, and a robust post-market strategy. The following recommendations are organized for manufacturers evaluating BtX potential or already pursuing designation.

1

Identify BtX potential early.

Assess the degree of novelty and the positive clinical impact vs. state of the art.

2

Engage your Notified Body through Structured Dialogue.

3

Engage regulators proactively.

Seek early advice for clinical development plans and evidence strategy.

4

Design lifecycle-based evidence plans.

Combine pre-market studies with PMS/PMCF/PMPF from the outset.

5

Strengthen post-market capabilities.

Invest in data collection systems and real-world evidence infrastructure.

6

Align global regulatory strategies.

Coordinate EU BtX with, for example, the FDA Breakthrough Device Program for US market access.

Key implications by manufacturer type

IMPLICATIONS FOR MD MANUFACTURERS

High-risk and novel technologies

Particularly relevant for: AI/ML-based software, implantable devices and advanced materials.

Design and development strategy

Manufacturers must integrate regulatory strategy early in development and ensure:

- Clear justification of novelty
- Demonstration of clinical impact

Post-market surveillance (PMS)

- Robust PMS systems required
- Structured PMCF programs essential
- Continuous benefit-risk reassessment

IMPLICATIONS FOR IVD MANUFACTURERS

The MDCG 2025-9 has significant implications for IVDs, particularly in areas such as:

Companion diagnostics (CDx)

There is a strong alignment required between diagnostic performance and therapeutic outcomes. In addition, BtX can facilitate earlier access while supporting post-market performance studies (PMPF).

Biomarker-driven and precision diagnostics

BtX framework supports innovative biomarker strategies and early clinical adoption with ongoing validation.

Real-world evidence integration

Greater reliance on registries and real-world datasets.

CONCLUSION

08

BtX Signals EU Regulatory Direction

What BtX signals about the direction of EU regulation, and why early movers will be better positioned for authorization, adoption, and lifecycle success.

MDCG 2025-9 represents a significant evolution in the European regulatory landscape, introducing, for the first time, a structured framework designed to both encourage innovation and maintain rigorous safety and performance standards, while enabling earlier patient access to high-impact technologies.

For manufacturers, the key shift is from *“How much evidence do we need before market?”* to *“How do we strategically generate evidence across the product lifecycle?”* This lifecycle-based approach places greater emphasis on the integration of pre-market and post-market evidence, aligning regulatory expectations with the realities of developing novel technologies. Success under this framework will depend on early planning, strong regulatory engagement, and a robust post-market strategy. But do remember: the BtX designation does not make approval easier – it makes innovation more feasible by redefining when and how evidence is generated.

Despite its strategic value, the number of BtX designations within the European Union is expected to remain limited, likely restricted to a small number of devices each year. This contrasts sharply with the U.S. FDA's Breakthrough Devices Program, which routinely grants more than one hundred designations annually. This stark difference reflects structural and operational realities: the EU system relies on multiple notified bodies with uneven capacity, limited expert-panel throughput, and no centralized review authority equivalent to the FDA. In contrast, the FDA operates a single, well-resourced, centralized program with dedicated staff and established fast-track procedures. The EU's stricter separation between assessment and consultancy, combined with already stretched notified-body resources, further constrains throughput. As a result, BtX is expected to be highly selective, focusing on a very small number of devices addressing clear unmet medical needs, while the U.S. system can accommodate a much larger volume of breakthrough designations.

Looking ahead, the introduction of BtX is a positive signal for European innovation, offering a more agile and forward-looking regulatory mindset. Consultancy organizations such as Veranex may play a valuable role in helping manufacturers prepare high-quality evidence packages, structure early engagement materials, and facilitate productive discussions with notified bodies, while staying within the boundaries of what NBs can legally provide. This collaborative ecosystem could ultimately help accelerate safe, meaningful innovation for patients across Europe. Furthermore, the increased acceptance of lifecycle-based evidence generation suggests a broader regulatory trend, which may, over time, be reflected in future revisions of both the MDR and IVDR regulations.

References

- 1 **MDCG 2025-9**, Guidance on Breakthrough Devices (BtX). health.ec.europa.eu/document/download/edca94c7-62ab-4dd5-8539-2b347bd14809_en?filename=mdcg_2025-9.pdf
- 2 **European Commission**, Notified Bodies Survey on certifications and applications (data status 28 February 2026). health.ec.europa.eu/document/download/59b9d90e-be42-4895-9f6f-bec35138bb0a_en?filename=md_nb_survey_certifications_applications_en.pdf
- 3 **MDCG 2025-10**, Guidance on post-market surveillance. health.ec.europa.eu/document/download/a9ad86b7-1b8e-4bae-beb4-48b2b3ed2f05_en?filename=mdcg_2025-10_en.pdf
- 4 **EMA**, Expert panel support for breakthrough medical devices: pilot programme. ema.europa.eu/en/human-regulatory-overview/medical-devices/expert-panel-support-breakthrough-medical-devices-pilot-programme
- 5 **FDA**, Breakthrough Devices Program overview and statistics. fda.gov/medical-devices/how-study-and-market-your-device/breakthrough-devices-program
- 6 **FDA**, Breakthrough Devices Program Guidance and FD&C Act §515B implementation. fda.gov/regulatory-information/search-fda-guidance-documents/breakthrough-devices-program
- 7 **European Commission**, notified bodies for medical devices and related capacity information. health.ec.europa.eu/medical-devices-topics-interest/notified-bodies-medical-devices_en
- 8 **European Commission**, Joint Scientific Consultations. health.ec.europa.eu/health-technology-assessment/implementation-regulation-health-technology-assessment/joint-scientific-consultations_en
- 9 **HTACG**, Guidance for selection of medical devices and IVDs for JSC. health.ec.europa.eu/document/download/ecf883f0-4863-4014-a8a2-0cd898d2bd3a_en?filename=hta_md_ivd_guidance_en.pdf

Is Your EU Regulatory Strategy Ready for BtX?

Veranex works with medical device and IVD manufacturers to evaluate BtX eligibility, structure early regulatory engagement, and build integrated evidence plans that serve both regulatory and post-market lifecycle needs. To discuss your program, contact our EU Regulatory team.



SCAN TO CONTACT US
veranex.com/contact/project-request